

Message

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Subject: NEWS UPDATE: Suit Seeks HHS Formaldehyde Data (Inside EPA)

The Inside Story

Suit Seeks HHS Formaldehyde Data

Posted: August 7, 2012

The American Chemistry Council is asking a federal district court to order the Health & Human Services

Department (HHS) to hand over documents concerning the listing of formaldehyde in the Report on Carcinogens (RoC) that the group alleges HHS has failed to produce in violation of a Freedom of Information Act (FOIA) request and other laws.

The request is the latest industry effort to get HHS to produce documentation on how much the department might have used a worker exposure study linking formaldehyde exposure to elevated leukemia risk in justifying its listing of formaldehyde as a "known carcinogen" in the 12th RoC, a congressionally mandated biennial report from the interagency National Toxicology Program (NTP) that EPA and other agencies have used for regulatory purposes.

The study by University of California, Berkeley, researcher Luoping Zhang, which links Chinese workers' exposure to formaldehyde with precursors of leukemia, is the same one used by EPA in its 2010 draft formaldehyde Integrated Risk Information System (IRIS) assessment that claimed the chemical causes leukemia. But the National Academy of Sciences (NAS) in an April 2011 review found that EPA did not provide sufficient evidence to support that conclusion.

Industry and Republicans have called on EPA to adopt NAS' recommendations for the IRIS program, and formaldehyde has also served as a poster child in industry criticism of the RoC listing process, which it calls scientifically deficient and lacking in transparency.

Industry-backed scientists have raised questions about whether "exogenous" or environmental formaldehyde, as opposed to formaldehyde the body naturally produces, can cause leukemia. Users and producers of formaldehyde are particularly keen on clearing their product of any linkage to leukemia because the association drives a much stricter risk assessment than those based on the more widely accepted nasal and nasopharyngeal cancers.

ACC writes in a [July 12 complaint](#) to the U.S. District Court for the District of Columbia that it asked HHS' National Institutes of Health (NIH) in a November 2011 FOIA request to hand over "copies of all records related to" the Zhang study, "including those records associated with the grants that provided funding for the Study." The grants for the study came from NIEHS and in the form of intramural funds from the National Cancer Institute (NCI).

"Despite explicit references to NCI in both the Zhang Study and Plaintiff's November 7, 2011 request -- and the fact that numerous NCI scientists co-authored the research article regarding the Zhang Study -- NIH referred Plaintiff's request only to Defendant [National Institute of Environmental Health Sciences] for response. Accordingly, Defendants did not search the records of any NIH entity other than NIEHS for information responsive to the request." ACC writes in its complaint that NIH also should have requested records from the grantees.

ACC writes that it takes issue with NIH's assertion that the additional information sought fail to meet key federal criteria for disclosure, including that it was "cited publicly and officially by the federal government in support of an agency action that has the force and effect of law." ACC argues, however, that the publication of the 12th RoC "has had the force and effect of law, including corresponding regulatory obligations. A federal law requires HHS to issue the RoC for use, *inter alia*, by federal regulatory authorities."

"For example, the Occupational Safety and Health Administration requires manufacturers of formaldehyde to obtain or develop material safety data sheets containing information with respect to formaldehyde's classification as a carcinogen," ACC writes. EPA also uses the cancer risk data from NTP as the basis for listing releases that facilities must report to its Toxics Release Inventory.

HHS officials have defended the RoC, saying that NTP is adhering to its congressional mandate while rejecting industry's contention that the listing process isn't transparent. NTP and NIEHS chief Linda Birnbaum, for instance, has said that the document is not regulatory in and of itself and that the document must, per Congress'

directive, list chemicals that are "known" or "reasonably anticipated" to be carcinogens. Birnbaum also has said that expert panel opinions and hundreds of peer-reviewed studies were considered.

Congress, meanwhile, has directed NAS to conduct a peer review of the listing of formaldehyde and the separate listing of styrene as "reasonably anticipated" to be a carcinogen. Birnbaum has said HHS' Office of the Assistant Secretary of Health hopes to have a contract in place with NAS by the end of fiscal year 2012.

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